

COLORADO STATE BOARD OF PHARMACY
January 15, 2009

Minutes

The Colorado State Board of Pharmacy meeting was convened by President Paul Limberis, R.Ph., at approximately 8:36 a.m. on Thursday, January 15, 2009 at 1560 Broadway, Conference Room 1380, Denver, CO 80202. Notice of this meeting was given in accordance with Division of Registrations Policy Number 80-17.

Board members attending were: Mary K. Arceneaux, R.Ph., Jeannine G. Dickerhofe, R.Ph., Rich Doyle, R.Ph., Katherine Edelblut, R.Ph., Leonard Hierath, P.E., Paul Limberis, R.Ph., and Averil Strand, R.N.

Staff members attending were Wendy Anderson, R.Ph., Program Director; Chris Gassen, R.Ph., Chief Inspector; Billie Marseilles, R.Ph., Inspector, Susan Martin, R.Ph., Inspector; and Mark O'Neill, R.Ph., Inspector. Also present was Jo Kaye, Assistant Attorney General, to advise the Board.

APPROVAL OF MINUTES

The Board approved the minutes from the November 20, 2008 meeting, as amended.

ADDITIONS TO THE AGENDA

Case 2009-1899, Parag Sheth, IN 2003255

Request from Kevin Broussard, R.Ph. 16027

Administrative Policies 30-4 through 30-9

APPEARANCES

None

HEARINGS

The Board conducted a public hearing concerning additions to or amendments to the following regulations: 6.00.00, 11.00.00, and 22.00.00 (3 CCR, 719-1). The hearing began at 9:30 a.m. and was held in Conference room 1380 at 1560 Broadway, Denver, Colorado. The Board discussed the proposed changes to the rules then adopted the rule as amended.

REPORTS

President's Remarks

President Paul Limberis reported on the American Society of Health-Systems Pharmacists Meeting in Orlando, Florida held in December 2008.

Program Director's Report

The Board reviewed a memorandum from Board staff and approved the Division of Registrations reception area and the internet as being the appropriate venues to post public notices of the Board's meetings for 2009.

The Board then reviewed amendments to Board Policy 20-12, "Board Criteria to Identify Nonresident Pharmacy Applications which Require Board Review" and new policy 40-7, "Changes to Schedule II controlled Substance Orders." After due consideration, the Board voted to adopt amendments to Policy 20-12 and new Board policy 40-7.

The Board discussed amendments to Board rule 9.00.00 titled "Legal Proceedings" After discussion and offering additional language, the Board voted to move rule 9.00.00 to hearing.

Ms. Anderson then discussed budget issues with the board. She explained that with the current budgetary constraints, a meeting devoted solely to planning was not feasible. She suggested that one planning item be added to each upcoming Board agenda. In addition, she requested the Board consider which Board meetings would be suitable for cancellation. The Board decided to cancel its February 2009 meeting. Ms. Anderson then stated that it was very likely that any State paid out of state travel would be cut. Consequently, that it was unlikely that the State would pay the expenses for a Board member to attend the National Association of Boards of Pharmacy ("NABP") Annual Meeting to be held in Miami in May 2009. She did state, however, that the voting delegate was eligible to receive a \$1200 travel grant from NABP. The application for the travel grant must be submitted to NABP no later than March 1, 2009. Ms. Anderson agreed to e-mail members when she had more information about travel.

Ms. Anderson and Ms. Dickerhofe discussed the NABP Symposium held in Tucson, Arizona in December 2008. The Symposium focused on counterfeit drugs and a Behind the Counter class of drugs. Ms. Anderson stated that California has postponed full implementation of pedigrees until 2016.

Mr. O'Neill then advised the Board that the next Pharmacy Manager Seminar would be held at the Board's offices on March 4, 2009 and requested that the district managers for the various organizations in attendance notify their employees.

Ms. Anderson then discussed the inspection requirements for the licensing or registration of non-resident pharmacies and out of state wholesalers. After due consideration, the Board decided that Board staff could extend the inspection requirement to five years from the date of the application, rather than the two-years that has been previously utilized.

Ms. Anderson then handed out numerous proposed policies for Board staff to administratively handle various issues. After due consideration, the Board adopted the following policies:

- 30-4 Security Violations
- 30-5 Unregistered/Unlicensed Activity
- 30-6 Designated Representative Changes
- 30-7 Prescription Drug Monitoring Program—Pharmacies that Fail to Register and Submit Data
- 30-8 Prescription Drug Monitoring Program—Pharmacies that Fail to Submit Data to the Prescription Drug Monitoring Program

30-9 Pharmacist Manager Changes

The Board then directed staff to work with counsel on a policy whereby staff could administratively deny the applications of businesses which had prior Cease and Desist Orders for unlicensed/unregistered activity. Board staff would then be authorized to offer the applicant a stipulated license with the payment of a non-negotiable \$5000 fine and agreement to future compliance with applicable Colorado laws and rules. The Board then delegated the final approval of this policy to Board President Paul Limberis.

Colorado Pharmacists Society (CPS) – Rich Doyle, RPh

Mr. Doyle reported that the next continuing education program is the 17th Annual Winter CE Seminar, January 18-21, 2009 at the Sheraton Steamboat Springs, where 15 hours of CE will be provided. Details are available on the CPS website www.copharm.org.

Advances in Pharmacy Practice, a continuing education program offering 6 hours of continuing education, is being offered by CPS and the School of Pharmacy on February 21, 2009.

Planning has already begun for the Annual Summer Meeting, June 26-28, 2009 in Copper Mountain Colorado where 10 hours of continuing education will be offered.

Pharmacist Line 9 has been incorporated into the 9 News schedule as an every other month event. This event is promoted during the news and the public is encouraged to call a number shown on the screen to speak to a pharmacist. Over 180 calls were received during the two hour session on December 15, 2008. The next Pharmacist Line 9 will be in February 2009. If you are interested in participating in this event, please contact the CPS office at 303-756-3069.

Governor's Expert Emergency Epidemic Response Committee (GEEERC) – Paul Limberis, RPh

The GEEERC met on Tuesday, January 6, 2009 at the Colorado Department of Public Health and Environment ("CDPHE"). Paul Limberis, committee member and Jeanine Dickerhofe, functional backup attended. This was the first meeting that was also able to be attended via a web conference. Several members participated in this manner. Updates included the following:

1. A Bio Watch Incident during the Democratic National Convention ("DNC"). This involved a federal program first implemented in 2002. Sensors that gather air, and reach a certain threshold are then analyzed for bio-active agents. Bio Watch Sensors were set up by the Secret Service around the Pepsi Center for the DNC. One of them had a "hit" for Tularemia in the Hot Zone, on the day of the acceptance speech. Following the phase I testing, all other results were negative. It was decided as a graded response at approximately 2:30 PM that this was a non-issue as this was a single hit and the agent is endemic to Colorado.
2. Crisis Informatics – The CDHPE is now working with a University of Colorado Research Program in mobile communications on developing programs for instant messaging using new Social Media tools. These include Flickr, Picassa, Twitter, and Microblogging. Mobile Texting is now used much more than voice

communication. These tools are being tested and set up for communication during and after a disaster. The Situational Analysis Tool ("SAT"), is already up and running on the CDHPE website.

3. WMD Report – World at Risk document. Recommendations from the document stress not only prevention of biological weapons, but a public health preparedness response as well. Paul and Jeanine have the document, should any members of the board like a copy.
4. Avian Influenza Update – The 2008 records show that there were 40 human cases of H5N1 Avian Flu documented with 30 of those resulting in death. The Colorado operating plan was submitted in July 2008 and the state is waiting on its final score. It was noted that this is the second highest planning scenario of the Governor's Office of Homeland Security. The GEEERC will continue to involve all state agencies to enhance the state level planning of this initiative.
5. Antiviral Update – As was done last year, Colorado will not participate in the stockpile purchase of Tamiflu. Many states will need to discard their stocks next year due to expiration dating. The GEEERC supports the decision based upon the data that show that only 8% of the population would be helped with the drug therapy and 73% benefit from social distancing programs which the GEEERC has focused its efforts on. However, the contract is still extended to hospitals and health departments to be able to purchase Tamiflu should they wish to do so.

Intern & School Relations – Jeannine Dickerhofe, RPh

Cathy Jarvis from the University of Colorado School of Pharmacy reported budgetary concerns for the School. She stated that budget cuts would occur in the next fiscal year. She stated that the number of applicants for the 2009 fall class has decreased to approximately 1000. The class size will be 160 students.

Legislation - Jeannine Dickerhofe, RPh.

Five bills introduced in the 2009 Legislative Session are being monitored to determine what impact they may have on pharmacy. The bill of greatest interest is HB 1032, concerning a requirement for photo identification in order to receive delivery of a controlled substance prescription. This bill would require the pharmacist to request a photo ID of any person picking up a controlled drug prescription, and then documenting on the back of the prescription, the person's full name, address and telephone number and retain this information for a period required by the DEA rules and regulations.

This bill was discussed extensively by the Colorado Pharmacy Coalition and a decision was made to meet with the bill sponsor, Representative Liston, to discuss the Coalition's concerns.

A draft of the Syringe Exchange Program bill authorizes each county in the state to accept and review an application from a health organization seeking to create a clean syringe exchange program. The bill will be introduced later in the legislative session.

The Prescription Project seeks to eliminate conflicts of interest created by industry marketing by promoting policy change among academic medical centers, professional medical societies and public and private payers. They plan to introduce a bill that would prohibit the commercial use of prescriber data, including that used for pharmaceutical detailing. This practice, commonly known as “data mining” is a key tactic used by pharmaceutical companies to tailor their marketing campaigns to individual doctors.

Rules – Rich Doyle

None.

Inspectors

None

OLD BUSINESS

Stipulations

Donnelly, Jennifer, RPH 15866

The Board reviewed an Agenda Memorandum from Tia Johnson, Complaint/Licensing Analyst, concerning Ms. Donnelly’s request for discharge from the terms of her Stipulation and Final Agency Order. After due consideration of the available information, the Board released Ms. Donnelly from her stipulation.

Hendrick, James S., RPH 11256

The Board reviewed an Agenda Memorandum from Ms. Johnson. After due consideration of the available information, the Board directed a letter be sent to Mr. Hendrick reminding him that he must receive a passing score on the ProBE ethics course by 10/23/09 to remain in compliance with his stipulation.

Jones, Tony E., RPH 14967

The Board reviewed correspondence submitted from Mr. Jones, and an Agenda Memorandum from Chris Gassen, Chief Inspector. Upon review the Board directed a letter be sent to Mr. Jones informing him of resources to obtain continuing education on the subject of the prevention of dispensing errors, and denied Mr. Jones’ request for staff approval of his future request for release from the terms of his stipulation.

Broussard, Kevin A., RPH 16027

The Board reviewed a request from Mr. Broussard in which he requested to be allowed to surrender his Colorado pharmacist license, and referred the matter for the drafting of a new stipulation.

MISCELLANEOUS

Combination Products and Corresponding Pedigree Requirements

The Board reviewed a Memorandum from Mr. Gassen and noted additional information from the Guidance for Industry on Prescription Drug Marketing Act (PDMP) from November 2006. After careful consideration of all available information, the Board determined that pedigree requirements would apply to “combination products” in cases where a prescription drug is a component of the combination product.

Innovation Associates & The PharmAssist Packaging / Dispensing System

The Board noted the information.

PharMerica, Rule 11.04.10 and Request for Extension

The Board approved PharMerica's request for an extension to comply with rule 11.04.10 until January 31, 2009 and requested that it submit correspondence to the Board demonstrating completion.

Complaints

Aubermann, John F., RPH 11244

2009-1376

After due consideration of the available information, the Board voted to issue a Letter of Admonition for violations of the Pharmaceuticals and Pharmacists Act and Board regulations.

Bio-Medical Resources, Inc., unregistered

2009-1897

A motion was made, seconded, and carried to dismiss the case, upon the receipt of an In State Prescription Drug Wholesaler registration from Bio-Medical Resources, Inc.

Chapman, Donald H., RPH 10299

2009-1400

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Chung, James H., RPH 15837

2009-1399

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Colorado Acute Long Term Hospital, PDO 424

2009-1953

After due consideration of the available information, the Board voted to refer the case for discipline.

Gambro Renal Products, Inc., WHI 6032

2009-1670

After due consideration of the available information, the Board voted to refer the case for discipline.

Hansman, Lien T., RPH 17196

2009-1564

Jeannine G. Dickerhofe, R.Ph. recused.

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Hanson, Gregory J., RPH 16303

2009-1385

After due consideration of the available information, the Board voted to issue a Letter of Admonition for violations of the Pharmaceuticals and Pharmacists Act and Board regulations.

Health Trans Pharmacy, PDO 634

2009-1375

After due consideration of the available information, the Board voted to refer the case for discipline.

Houston, Lisa M., RPH 16333 **2009-1388**

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Jung, Madelyn M., RPH 15046 **2009-1377**

After due consideration of the available information, the Board voted to issue a Letter of Admonition for violations of the Pharmaceuticals and Pharmacists Act and Board regulations.

Lawton, Leslie A., RPH 14371 **2009-1089**

A motion was made, seconded, and carried to dismiss the case as being without merit. However the Board did direct a letter of guidance be sent to Ms. Lawton.

Le, Brian T., RPH 14758 **2009-1396**

After due consideration of the available information, the Board voted to issue a Letter of Admonition for violations of the Pharmaceuticals and Pharmacists Act and Board regulations.

Lodwick, Algha D., RPH 11071 **2009-3838**

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Mankarious, Ezzat S., RPH 15510 **2009-1386**

After due consideration of the available information, the Board voted to issue a Letter of Admonition for violations of the Pharmaceuticals and Pharmacists Act and Board regulations.

McClure, James J., RPH 16526 **2009-1380**

After due consideration of the available information, the Board voted to issue a Letter of Admonition for violations of the Pharmaceuticals and Pharmacists Act and Board regulations.

Murray, Troy H., RPH 14218 **2009-1395**

After due consideration of the available information, the Board voted to issue a Letter of Admonition for violations of the Pharmaceuticals and Pharmacists Act and Board regulations.

NMHCRCX Mail Order, Inc., OSP 5494 **2009-1112**

After due consideration of the available information, the Board voted to refer the case for discipline.

Ortolani, Jennifer H., RPH 17242 **2009-1027**

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

South Platte Vet Supply, WHI 6025 **2009-1533**

Rich Doyle, R.Ph. recused.

After due consideration of the available information, the Board voted to refer the case for discipline.

Schroeder, William O., DVM, Unregistered **2009-1535**
Rich Doyle, R.Ph. recused.

After due consideration of the available information, the Board voted to issue a Cease and Desist Order for unregistered practice.

Coakley, Michael J., DVM, Unregistered **2009-1536**
Rich Doyle, R.Ph. recused.

A motion was made, seconded, and carried to dismiss the case as being without merit.

Ivesco Holdings, LLC, WHO applicant **2009-1534**
Rich Doyle, R.Ph. recused.

After due consideration of the available information, the Board voted to issue a Cease and Desist Order for unregistered practice.

Senn, Joseph D., RPH 13725 **2009-1389**
Jeannine Dickerhofe, R.Ph. recused.

A motion was made, seconded, and carried to table this case, pending additional information.

St. Vincent General Hospital District, PDO 77-2 **2009-1498**
After due consideration of the available information, the Board voted to refer the case for discipline.

Wal-Mart Pharmacy # 10-4335, PDO 693 **2009-1306**
After due consideration of the available information, the Board voted to refer the case for discipline.

Warren, Jennifer L., RPH 13845 **2009-1166**
A motion was made, seconded, and carried to dismiss the case as being without merit.

Sheth, Parag M., IN 2003255 **2009-1899**
After due consideration of the available information, the Board voted to refer the case for discipline.

LICENSING

Other Outlets, New

The Board approved the registration of 3 new other outlets.

Prescription Drug Outlets, New (In-State)

The Board approved the registrations of 2 new in-state prescription drug outlets.

Prescription Drug Outlets, New (Out-of-State)

The Board approved the registrations of 9 new nonresident prescription drug outlets.

Manufacturers, New

The Board approved the registrations of 2 new manufacturers.

Limited Licenses, New

The Board approved the registrations of 0 new limited licenses.

Wholesalers, New (In-State)

The Board approved the registrations of 2 new in-state Wholesalers.

Wholesalers, New (Out-of-State)

The Board approved the registrations of 19 new out-of-state Wholesalers.

Licensure by Examination

The Board ratified the licensure of 11 applicants for licensure by examination.

Licensure by Score Transfer

The Board ratified the licensure of 0 applicants for licensure by score transfer.

Licensure by License Transfer

The Board ratified the licensure of 28 applicants seeking licensure through license transfer. It was noted that these licensees met all of the requirements for licensing under the provisions of section 12-22-116, C.R.S.

Licensure Issues

Miscellaneous

Governski, Robert A., RPH 14225

Mary K. Arceneaux, R.Ph. recused.

This matter was tabled pending additional information.

Butler Animal Health Supply, Out of State Wholesaler Applicant

After review of the available information, the Board voted to deny the application, referring the matter for discipline.

Ivesco Holdings LLC, Out of State Wholesaler Applicant

After review of the available information, the Board voted to deny the application, referring the matter for discipline.

McKesson Corporation, Out of State Wholesaler Applicant

After review of the available information, the Board voted to deny the application.

RPK Pharmaceutical, DBA Pharmedix, Out of State Wholesaler Applicant

After review of the available information, the Board voted to deny the application, referring the matter for discipline.

Top RX, Inc., WHO 7051, Application for Change of Location

The Board directed the processing of the Change of Location application.

Basic Home Infusion, Non-Resident Prescription Drug Outlet Applicant

This matter was tabled pending additional information.

Kindred Pharmacy Services, Non-Resident Prescription Drug Outlet Applicant

After review of the available information, the Board voted to issue the registration

Providence Specialty Pharmacy Services, Non-Resident Prescription Drug Outlet Applicant

This matter was tabled pending Board approval of the quality assurance plan the above-referenced applicant had previously submitted to the Oregon Board of Pharmacy. The Board then authorized Board staff to approve the registration of the pharmacy should the plan be acceptable to Board staff.

Norgauer, Frank J., Pharmacist Applicant

After review of the available information, the Board voted to issue the license.

MISCELLANEOUS

Correspondence, etc.

Apothecare Pharmacy's Proposed Travel Health Clinic & Rule 6.00.00

After due consideration, the Board denied Apothecare Pharmacy's request and directed additional information be sent to the pharmacy concerning Rule 19.00.00.

NABP to Launch New Computerized FPGEE at April 2009 Administration

The Board noted this information.

Omnicare of Golden and Rule 11.04.10

After due consideration, the Board directed Omnicare of Golden to come completely into compliance with Rule 11.04.10 within six months, and requested that the pharmacy submit a letter to the Board demonstrating the pharmacy's compliance.

Peak Vista Family Health Center at Myron Stratton and Petition to Reduce Visitation Schedule Pursuant to Rule 14.06.00(a)

This matter was tabled pending additional information.

EXECUTIVE SESSION

Board President Paul Limberis moved that the Board enter into executive session as authorized by CRS 24-6-402 subsection (3)(a) roman (III) to discuss matters which are required by law to be kept confidential. Specifically, the provisions of law requiring these matters to be kept confidential are:

CRS 24-6-402 subsection (3)(a) romans (II) and (III), and section 13-90-107(b), which protect as confidential communications with counsel that are matters of pending or imminent litigation, or are otherwise subject to the attorney-client privilege, and CRS 25-1-

1201 et sequitor, which protects the confidentiality of information pertaining to individual medical records.

The motion was unanimous.

The Board discussed the case status report from the Office of Expedited Settlement.

The Board discussed the report from the Rehabilitation Evaluation Committee ("REC").

The Board discussed all items referred to it earlier in the meeting as well as matters confidential by law.

Open Session

The Board voted to accept PR08-KB into the REC upon receipt of an application.

2009-1345

A motion was made, seconded, and carried to dismiss the case as being without merit.

The Board directed a letter be sent to Wal-Mart Pharmacy # 10-0905 and to Wal-Mart's corporate office concerning their policy regarding the merging of patient profiles.

2009-1492

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

2009-0811

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

ADJOURNMENT

The Board adjourned at approximately 5:45 p.m.

Approved by Paul Limberis, R.Ph., President Date: March 19, 2009